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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,526	08/24/2006	Tatsuhiko Kodama	295060US0PCT	9779

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EXAMINER	
WANG, CHANG YU	

ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
12/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/590,526	KODAMA ET AL.	
	Examiner	Art Unit	
	CHANG-YU WANG	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RESPONSE TO AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/2/09 has been entered.

Status of Application/Amendments/claims

2. Applicant's amendment filed 10/2/09 is acknowledged. Claims 1-20 are cancelled. Claims 21-36 are newly added. New claims 21-36 are pending in this application and under examination in this office action.

3. Any objection or rejection of record, which is not expressly repeated in this office action, has been overcome by Applicant's response.

4. Applicant's arguments filed on 10/2/09 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections/Objections Withdrawn

5. The rejection of claims 1-7 and 12-15 under 35 U.S.C. 102 (b) as being anticipated by Peri et al. (Circulation. 2000, 102:636-641 as in IDS) is moot because the claims are canceled.

The rejection of claims 1-7 and 12-15 under 35 U.S.C. 102(a) & (e) as being anticipated by US2004/0137544 (Latini et al., published Jul 15, 2004, priority Oct 31, 2002) is moot because the claims are canceled.

The rejection of claims 1-7 and 12-15 under 35 U.S.C. 102 (a) as being anticipated by Latini et al. (Circulation 2004, 110:2349-2354, as in IDS) is moot because the claims are canceled.

The rejection of claims 16-20 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement due to new matter is moot because the claims are canceled.

Claim Rejections/Objections Maintained

In view of the amendment filed on 10/2/09, the following rejections are maintained.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diagnosis of coronary artery condition (CA), unstable angina (UAP) and myocardial infarction (AMI) by measuring an increased level of PTX3 using an anti-PTX antibody in patients with the above conditions as compared to defined controls, does not reasonably provide enablement for a method for assessing the extent of vascular injury in a subject who has not had a myocardial infarction or no

cardiovascular disease, or no cerebrovascular disease, or who have been diagnosed as having diabetes, hyperlipidemia, cerebral disease, hypertension, obesity or smoking by determining the level of PTX3 including using an anti-PTX3 antibody wherein the extent of vascular injury is described by undefined histological parameters recited in independent claim 21 as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The rejection of claims 1-7 and 12-20 under 35 U.S.C. 112, first paragraph, because the specification does not enable the invention commensurate in scope with the claims is moot because the claims are canceled. However, the rejection is applied to new claims 21-36 for the same reasons of record because new claims 21-36 are within the scope of the rejected claims 1-7 and 12-20.

Claims 21-36 are drawn to a method for assessing the extent of vascular injury in a subject who has not had a myocardial infarction, no cardiovascular disease, or no cerebrovascular disease, or who have been diagnosed as having diabetes, hyperlipidemia, cerebral disease, hypertension, obesity or smoking by determining the level of PTX3 including using an anti-PTX3 antibody compared to a control value wherein an increased level of PTX3 in the blood of the subject compared to the control value is indicative of vascular injury; wherein the extent of vascular injury is described by at least one of the following histological parameters (a) lipid core size, (b) thickness of fibrous cap, (c) strength of shear stress and (d) extent of inflammatory infiltration and wherein the test sample is blood, serum or plasma.

On p. 5-6 of the response, Applicant argues that the rejection is moot because the rejected claims have been canceled. Applicant argues that the rejection would not apply to the new claims because new claims recite an increased level of pentraxin with respect to a control value. Applicant argues that the use of control values is known in the art and cites Peri et al. (Circulation. 2000. 102:636-641) and Latini et al. (US2004/0137544) in support of the arguments. Applicant argues that the skilled artisan eg. A medical doctor, would know how to determine a relative level of PTX3. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, the rejection still applies to new claims because new claims are within the same scope of the previously rejected claims. As previously made of record, the specification fails to teach the relationship between the levels of PTX3 and the histological parameters of the lipid core size, thickness of fibrous cap, strength of shear stress and the extent of inflammatory infiltration. The instant specification fails to teach what levels of PTX3 are correlated to what degrees of the recited histological parameters (lipid core size, thickness of fibrous cap, strength of shear stress and the extent of inflammatory infiltration) in patients who are suffering from all forms of vascular injury and have no myocardial infarction, no cardiovascular disease, or no cerebrovascular disease, or who have been diagnosed as having diabetes, hyperlipidemia, cerebral disease, hypertension, obesity or smoking as recited in instant claims.

The instant specification only shows that the level of PTX3 in the blood of patients suffering from CA, UAP and AMI is higher and the pathological conditions of

these patients are severe as compared to patients without CA, UAP and AMI. There is no guidance or no correlation between the levels of PTX3 and the extent of different histological parameters in different diseases. There is no guidance as to how the levels of PTX3 would affect the recited histological parameters. There is no guidance as to how other diseases correlates to CA, UAP and AMI and how the recited histological parameters in patients with CA, UAP and AMI correlates to those in patients with other diseases or with the recited conditions. The skilled artisan cannot contemplate how to use the claimed invention because it is unknown what specific levels of PTX3 can be used as an indicator of the extent of different forms of the undefined vascular injury.

In addition, the specification fails to define what value or criteria would be considered as a control value and thus can be used in the claimed method. Furthermore, there is no guidance of the relationship between different diseases and the diseases of CA, UAP and AMI. Thus, a skilled artisan cannot contemplate the control value and cannot contemplate the correlation between the levels of PTX3 in CA, UAP and AMI and the levels of PTX3 in other recited diseases and thereby to assess the extent of vascular injury.

The instant methods are directed to assessing the extent of vascular injury based on the relationship between the histological condition and the expression level of PTX3. The specification fails to teach what the specific level of PTX3 as an indicator of the extent of vascular injury is. The specification also fails to teach the expression levels of PTX3 in patients who have been diagnosed with no myocardial infarction, no dementia in relation to a cerebrovascular disease or who has hyperlipidemia, cerebral disease,

hypertension, diabetes, obesity or smokes. Note that Applicant cannot use an unknown parameter (an unknown level of PTX3) to determine another unknown outcome from the recited pathological conditions. Note that

"The 'predictability or lack thereof' in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. In particular, the court in In re Marzocchi, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971)" See MPEP § 2164.03

In addition, a patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not follow the guidance presented therein and practice the claimed method without first making a substantial inventive contribution.

7. Claims 21-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection of claims 1-7 and 12-20 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is moot because the claims are canceled. However, the rejection is applied to new claims 21-36 for the same reasons of record because new claims 21-36 are within the scope of the rejected claims 1-7 and 12-20.

On p. 6-7 of the response, Applicant argues that Applicant is in possession of the claimed methods of assessing all types of vascular injury because the specification discloses different conditions on p. 8, line 15 and p. 8-9. Applicant argues that measuring PTX3 levels are described on p. 6, lines 3-5. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, as previously made of record, the specification fails to teach the correlation between the diseases of CA, UAP and MCI, and other undefined vascular diseases. In addition, the specification fails to describe what a defined control value recited in independent claim 21 is. There is no specific correlation between the recited histological parameters or the recited control value and the levels of PTX3. Thus, a skilled artisan cannot envision the functional correlation between the claimed diseases and the claimed invention. Accordingly, the specification fails to reasonably demonstrate that Applicant is in possession of the claimed method as currently written. Note that

A definition by function alone "does not suffice" to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Eli Lilly*, 119 F.3 at 1568, 43 USPQ2d at 1406. See also *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen Inc. v.Chugai Pharmaceutical* Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)). An adequate written description of a chemical invention also requires a precise definition, such as by structure,

formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle &Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004).

Obviousness-Type Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 12/092272. The provisional rejection of claims 1-7 and 12-15 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 12/092272 is moot because the claims are canceled. However, the rejection is applied to new claims for the same reasons of record because new claims 21-36 are within the scope of the rejected claims 1-7 and 12-20.

On p. 8-9 of the response, Applicant argues that the rejection is moot because the claims are cancelled. Applicant argues that the forgoing amendments and remarks address all the remaining rejections and place the instant application in condition for

allowance. Applicant argues that based on MPEP 804 (I)(B), the instant provisional rejection can be withdrawn because the pending applicant has not been allowed. Applicant's arguments have been fully considered but they are not persuasive.

In contrast to Applicant arguments, new claims are not allowable and the amendment and the remark haven't overcome the remaining rejections. Thus, the ODP rejection is maintained of record until a terminal disclaimer is filed.

New Grounds of Rejection Necessitated by the Amendment

The following rejections are new grounds of rejections necessitated by the amendment filed on 10/2/09.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-29 and 31-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21-29 and 31-36 are indefinite because Claim 21 recites the limitation "in the blood" in line 5 of the claims. There is insufficient antecedent basis for this limitation in the claim. The rest of the claims are indefinite as depending from an indefinite claim 21.

Conclusion

10. NO CLAIM IS ALLOWED.

11. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chang-Yu Wang, Ph.D.
December 10, 2009

/Chang-Yu Wang/
Examiner, Art Unit 1649